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|--|----------------------|-----------------------|---------------------|------------------|
| 10/678,371 | 10/03/2003 | Benjamin V. Treadwell | 030229 | 4023 |
| 26285 7590 12/21/2006 KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP 535 SMITHFIELD STREET PITTSBURGH, PA 15222 | | | EXAMINER | |
| | | | KIM, JENNIFER M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | · |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 31 D | AYS | 12/21/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| | Application No. | Applicant(s) | |
| | 10/678,371 | TREADWELL, BENJAMIN V. | |
| Office Action Summary | Examiner | Art Unit | |
| · | Jennifer Kim | 1617 | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet w | ith the correspondence address | |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN R 1.136(a). In no event, however, may a riod will apply and will expire SIX (6) MO atute, cause the application to become A | CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | |
| Status | • | | |
| 1) ☐ Responsive to communication(s) filed on ② 2a) ☐ This action is FINAL . 2b) ☐ T 3) ☐ Since this application is in condition for alloclosed in accordance with the practice under | This action is non-final. wance except for formal ma | · | |
| Disposition of Claims | · | | |
| 4) ☐ Claim(s) 1-64 is/are pending in the applicat 4a) Of the above claim(s) is/are without 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-64 are subject to restriction and/ | drawn from consideration. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Exam | niner | | |
| 10) The drawing(s) filed on is/are: a) a | | by the Examiner. | |
| Applicant may not request that any objection to | the drawing(s) be held in abeya | nce. See 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the con | , | • | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the papplication from the International Bur * See the attached detailed Office action for a | ents have been received. ents have been received in a priority documents have been reau (PCT Rule 17.2(a)). | Application No n received in this National Stage | |
| | | | |
| Attachment(s) | _ | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | Paper No | Summary (PTO-413) s)/Mail Date Informal Patent Application | |

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, drawn to a composition for attenuating at least one factor involved in the inflammation-associated destruction of tissue comprising a first component comprising a long-chain normal primary aliphatic alcohol, and a second component selected from the group consisting of a B12 Vitamin, a D vitamin, coenzyme Q, an omega-3 fatty acid and combinations thereof, classified in class 514, subclass 558.
- II. Claims 30-64, drawn to a method for attenuating one or more symptoms or risk factors associated with autoimmune disease or immuno-inflammatory disease in mammals comprising administering an effective amount of a composition comprising a first component comprising a long-chain normal primary aliphatic alcohol, and a second component selected from the group consisting of a B12 Vitamin, a D Vitamin, a coenzyme Q, an omega-3 fatty acid and combinations thereof, classified in class 514, subclass 558.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product since the product can be used to treat cancer.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If Applicant elects a single Group from Group I or II, following election of species is required because:

1) This application contains claims directed to the following patentably distinct species: various long-chain normal primary aliphatic alcohol (e.g. 1-triacontanol, 1-octacosanol, 1-heptacosanol.etc.). The species are independent or distinct because each of the alcohol has its own unique chemical/physical characteristics.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a long-chain normal primary aliphatic alcohol is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

2) This application contains claims directed to the following patentably distinct species: various B12 Vitamins (e.g. cyanocobalamine, methylcobalamine .etc.). The species are independent or distinct because each of the alcohol has its own unique chemical/physical characteristics.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a B12 Vitamin is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

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of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

3) This application contains claims directed to the following patentably distinct species: various D Vitamins (e.g. Vitamin D2, Vitamin D3, 1,25-dihydroxyvitamin D3, etc..). The species are independent or distinct because each of the alcohol has its own unique chemical/physical characteristics.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a D Vitamin is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species from each of 1), 2) and 3) with a single invention

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Group I or Group II, to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

If Applicant elects Group II, following additional election of species is required because

4) This application in Group II contains claims directed to the following patentably distinct species: multiple sclerosis and rheumatoid arthritis. The species are independent or distinct because each of the disease to be treated have different known treatment involving unrelated active compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, an autoimmune disease or immuno-inflammatory disease is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claims will not be rejoined. See MPEP 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk

December 12, 2006